

Remarks

Specification

The specification was rejected as failing to provide proper antecedent basis for the claimed subject matter, namely the term: "vacuum line." However, line 31 of page 4 of the specification does include the term "vacuuming line", which would be understood to be identical to the claimed term "vacuum line". To make this explicit line 31 of page 4 has been amended to read "vacuum line". This should obviate this rejection.

Obviousness

The sole remaining issue is whether the applicants' claims are rendered obvious in light of a combination of cited references and thus are not allowable under 35 USC § 103. An analysis of the cited references indicates that reconsideration is warranted.

To establish a prima facie case of obviousness, a teaching or suggestion to make the claimed combination and a reasonable expectation of success must both be found in the prior art, and not based on the applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

No proper teaching to combine is cited.

The obviousness rejections should be reconsidered because there is no proper teaching for the combination of the cited references. "Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight based obviousness analysis is a rigorous application of the requirement for a showing of the teaching or motivation to combine the prior art references." In re Dembiczak, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999) (internal citations omitted). "The showing must be clear and particular. Broad conclusory statements regarding the teaching of multiple references, standing alone, are not 'evidence'." The mere fact that

references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). In applying this law to the present claims, a finding of obvious should be reconsidered.

A. No clear and particular teaching to combine exists

The law requires a clear and particular teaching to be found in the cited references. Such a teaching must come from the references. In addition, broad conclusory statements are deemed not sufficient. However such broad conclusory statements are all that are proffered in the present Office action.

The present Office action in Section 11 notes:

"In the case, Harris et al. does provide teaching for the two movable tracks. Harris et al. cite that the instrument has two processing lines, which allow two different tests to be performed simultaneously (Col. 3, lines 36-38). . . This in itself is sufficient motivation."

The logic of this statement is not in accord with the cited rule. The Office action notes that Harris, like the applicants, use a first and second track. The Office action proposes that alone is suggested as motivation to combine with other references. However, the mere fact that a reference includes some of the elements of an examined claim plainly is not sufficient to form a clear and particular motivation to combine references. Were this true every reference that includes elements of a claim would then per se also teach combination with every other reference teaching other elements within a claim. Nothing, either from the prior art, or in knowledge generally available to one of ordinary skill in the

art has been cited as a clear and specific teaching for the combination of two dissimilar references.

The Office action notes that the two processing lines of Harris et al. "allow two different tests to be performed simultaneously". This is in contrast to both the applicants claimed device and the device of Adourian et al., neither of which teach a system in which two different tests are performed simultaneously. Instead Adourian et al. teaches a system in which a microfluidic substrate is positioned at a fixed location. A robotic arm moves to the fixed location to inject samples into the ports. Electrophoretic separation and optical analysis then occurs at the fixed location of the microfluidic substrate. The applicants disclose a system in which samples on a macrofluidic wells on a first track are transferred to microfluidic injection ports on a second track. The second track then moves the substrate to a remote location, where the samples in channels on the substrate are electrophoretically detected. Both Adourian et al. and the applicants perform a single assay, namely electrophoretic separation.

The text from Harris et al. teaches away from the cited combination by noting that Harris teaches a device used for a wholly different purpose (i.e. simultaneous performing two different assays) than that taught in Adourian et al. or that effected by the applicants' claims. The text cited in the Office action indicates that the references should not be combined.

B. Adourian et al. Specifically Teaches Away from the Combination with Harris

The premise of the present Office action appears to be that all laboratory instrumentation could be combined for no other reason than that they are all used in the laboratory. Yet nothing from the literature is cited to support this reasoning. It is not logical to think that a device to position a sample on a gel phosphoimager that images

macroscopic targets that are several millimeters large could be substituted into an electron microscope that images samples with a sub-micron resolution. The different resolutions of the systems requires different components to make the systems functional.

One of the cited references, Adourian et al., specifically notes that macroscopic and microscopic devices would not be compatible. Adourian states:

"Within the test module 32 is a microchip (also called an ME device). It should be understood that the automated features of the apparatus features 90 of Fig. 4 (as well as the apparatus of Fig. 1) provide a bridge between the conventional macroscopic format (millimeter geometries) of microtiter plates and the microscopic (micrometer geometry) format of ME devices. That is, the current invention solves this problem by close integration of a precision motion control system with the ME device. Both the motion control system and the ME device are specifically customized with microfabricated structures to achieve an efficient overall solution to the required format change."

This section of Adourian et al. plainly establishes a few facts. First, automated features that engage macroscopic geometries are significantly different from those that engage microscopic geometries. Second, specific technology is required to "bridge" the macroscopic to microscopic divide. Third, merely to move a loader to a stationary sample requires a specific "bridge" to span the gap between macroscopic and microscopic scales. Under the teaching of Adourian et al., a device for moving a microchip would also have to include specific adaptations to bridge this divide. In Adourian, the chip position does not change. All that is needed is a dispenser be accurately moved in relation to the chip. The applicants' claims are directed to a device in which not only must the loader be moved in relation to the chip, but also the chip is moved in relation to the loader and the chip is moved in relation to the analysis optics and

electrophoresis terminals. Thus the applicants' claims disclose a system in which the chip is moved first to an injection site where it must dock with a movable loader and then on the track to an analysis site. The "bridge" required by Adourian is not present in any of the cited references for the substrate moving track. For this reason these references cannot not be properly combined.

C. The Proposed Combination Renders Adourian Unfit for its Intended Purpose

Finally, the law states that a combination is not permissible if the combination of elements from one source would render the technology from the other cited source unfit for its intended purpose. The intended purpose of Adourian et al. is to load and analyze samples in channels in a substrate. The entry ports to the sample are very small and the amount of liquid dispensed is also very small.

The Office action finds:

"It is noted that Harris et al. provide for the teaching of the two tracks, and it does not matter whether smaller or larger samples are being dispensed. In fact, the size of the sample being dispensed is not affected by the larger system". This argument is not consistent with the cited law, which states that if the cited combination renders one reference unfit for its intended purpose, the combination is not proper. As noted in the previous response, the difference between the technology of Harris et al. and the technology of Adourian et al. goes far beyond the sample size. Adourian require dispensing into microscale openings into channels on a substrate. Further Adourian requires that cathodes and anodes provide a current through the channels to separate the samples. Finally, the samples must be positioned within the optical imaging area. In all of these cases, precise positioning is critical. As noted in the previous response, this is clearly set out in the cited references. Adourian et al. discloses that macroscopic and microscopic

technologies are of a sufficiently different nature as to require specific teachings to adapt one to the other. If a device having the tolerances of Harris were combined with Adourian, it would not position the substrate with sufficient precision to either load the chip or connect to terminals by placing wires in the ports, or analyze the samples within channels in the substrate. Given these facts, the cited combination is not proper.

The Asserted References do not Render Obvious the Applicants' Claims

Even if the references are combined, this combination does not render obvious the applicants' claims. An obviousness determination requires determining the scope and content of the prior art and ascertaining the differences between the cited art and the claims at issue. See *Graham v. John Deere Co.*, 148 USPQ 459 (S.C. 1966). When applying 35 USC Section 103 in a finding of obviousness, the tenants of patent law require that the claimed invention be considered as a whole, that the cited references must suggest the desirability and thus the obviousness of making the claimed combination, that the cited references must be viewed without the benefit of impermissible hindsight afforded by the claimed invention, and that the cited reference provide a reasonable expectation of success in practicing the claimed technology. See *Hodosh v. Block Drug Co., Inc.*, 229 USPQ 182, 187 (Fed. Cir. 1986).

The present Office action notes "Adourian et al. do not specifically recite the use of movable first of second tracks for holding the microchip substrate and microtiter plate, respectively". The present pending claim 1 is even more specific, requiring a the gantry and tracks are positionable in relation to each other such that "said multifunctional device may be aligned to transfer liquid from a plurality of wells on the plate to a plurality of inlet

ports on the substrate". Such a claim requires a second track that is able to position a substrate (which the claim specifies is carried by the track) such that the sample dispenser may dispense into the microscale ports of the channels on the substrate. However, the subsequent citations from Harris et al. fail to provide such teachings. This again warrants reconsideration and withdrawal of the present rejection.

Conclusion

The applicants respectfully request reconsideration in light of the submitted remarks and amendments. A notice of allowance is earnestly solicited. If any matter relating to this case needs to be discussed please call our office at (408) 297-9733 between 9 a.m. and 5 p.m. Pacific time.

CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Alexandria, VA 22313

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Respectfully submitted,



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